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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

# WARNING LETTER

**FLA-05-20**

February 17, 2005

Robert J. Hicks, President
Everglades Fish Company L.L.C.
208 Camellia Street
Everglades City, Florida 34139

Dear Mr. Hicks:

On October 21 and 25, 2004, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the Seafood HACCP Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and Current Good Manufacturing Practice Requirements for Food (GMP), 21 CFR Part 110. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your ready-to-eat cooked stone crab claws, ready-to-eat cooked spiny lobster, and ciguatera toxin susceptible fresh finfish are adulterated in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the Seafood HACCP Regulations through links in FDA's homepage at http:// www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels". However, your firm's HACCP plans for:

    - Cooked stone crab claws and spiny lobster do not list the critical control point of refrigerated storage for controlling the food safety hazards of pathogen growth/toxin formation due to time/temperature abuse.

- Spiny lobsters does not list the critical control point of cooling for the control of the hazard of pathogen growth/toxin formation related to time/temperature abuse.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked spiny lobster lists a critical limit, "Established Process schedule", at the cooking critical control point that is not adequate to control pathogen survival. Your plan should include the specific cook time(s) and temperature(s) that are necessary to assure that the coldest spot in the largest lobsters and the largest batch size receives a cook sufficient to control the food safety hazard of pathogen survival through cooking.

3. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure, "Ask harvest location" and frequency of every lot, at the receiving critical control point to control the hazard of CFP listed in your HACCP plan for grouper and snapper. Our investigator noted that the "receipts of catch" that were provided to him as a monitoring record, did not include information that would permit your firm to reject grouper or snapper from areas closed or under advisory because of CFP.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Brant M. Schroeder, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Mr. Schroeder at (407) 475-4763.

Sincerely,

Emma R. Singleton
Director, Florida District